



UNITED STATES PATENT AND TRADEMARK OFFICE

107

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,113	03/02/2004	Kazuhiro Kikuchi	249426US	1147
22850	7590	11/04/2005		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,113

Applicant(s)

KIKUCHI ET AL.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 2 as amended (8/25/2005) are pending and under examination.

Response to Arguments

Applicant's arguments filed 8/25/2005 have been fully considered but they are not persuasive for the reasons below.

Claim Rejections - 35 USC § 112

Indefinite

Claims 1 and 2 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as amended is indefinite because it is unclear what compound(s) are required to be present (or added) in the claimed amounts. Is it acid or is it salt? The claimed concentration refers to an acid or to lactic acid that is added as 60% solution of a lactic acid. But if lactic acid is present in a form of sodium lactate, the amount of sodium lactate would be unclear or at the very least different from the amount of lactic acid.

New matter

Claims 1 and 2 as amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

Art Unit: 1651

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation “only a sodium salt as a lactic acid salt is present” in claim 1 has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of the use of only sodium salt of lactic acid.

The generic disclosure teaches the use of various salts of lactic acid including sodium, potassium and calcium salts and the generic disclosure also teaches that lactate salts may be used in combination, for example: page 6, par. 4. Thus, the generic disclosure does not provide written support for an exclusive use of only sodium lactate salt in a composition comprising culture medium for production of porcine embryo.

The exemplified and particular composition as intended for embryo culture medium (table 1, page 14) comprises various alkali metal salts and/or metal ions including sodium, potassium and calcium, magnesium. Thus, the exemplified disclosure of a culture medium composition for production of porcine embryo does not provide written support for an exclusive use (exclusive presence) of lactic acid component as only sodium lactate salt.

Therefore, there is no sufficient support for the new genus drawn to exclusive use or exclusive presence of lactic acid as only sodium lactate salt in a medium composition intended for embryo *in vitro* culture. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Art Unit: 1651

Declarations and new references cannot demonstrate the possession of a concept after the fact.

Thus, the insertion of limitation such as “only a sodium salt as a lactic acid salt is present” is considered to be the insertion new matter for the above reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Petters et al. (IDS reference; Journal of Reproduction and Fertility Supplement. 1993, 48:61-73) as explained in the prior office action and for the reasons below.

Claim is directed to a culture medium composition for in vitro produced porcine embryo culture wherein the medium composition comprises lactic acid or its salt and pyruvic acid or its salts, wherein the medium does not contain glucose, wherein the amount of lactic acid or sodium lactate is 0.25-5.5 µl/ml of a 60% solution (0.15-3 mg/ml) and wherein amount of pyruvic acid is 0.009-0.036 mg/ml.

The reference by Petters et al. is relied upon as explained in the prior office action and repeated herein.

Petters et al. disclose several culture medium compositions for in vitro produced porcine embryo (table 1, page 66 and table 3, page 69). For example: UB medium (table 3) does not contain glucose and it contains sodium lactate or lactic acid salt in amount 2.08 mmol/L (1.45

Art Unit: 1651

mg/ml) and pyruvic acid salt in amount 0.18 mmol/l (0.016 mg/ml). The amounts are within the presently claimed ranges. The Whitten medium c and d (table 1) also comprises sodium salts of lactic acid and pyruvic acid within the presently claimed ranges and it does not contain glucose as required by the claimed invention. Thus, the cited reference anticipates the claimed invention.

With respect to the reference by Petters et al applicants argue that the cited media comprise calcium lactate salt that is excluded from the presently claimed composition that requires only sodium lactate (response filed 8/25/2005, page 4). However, the cited media contain sodium lactate in the same amounts as presently claimed for the lactic acid that is present in a form of sodium lactate. The claimed medium composition is open to incorporation of additional salts of lactic acid by the virtue of open language ‘comprising’ and/or by the virtue of alternative and generic language “lactic acid or its salt”. Moreover, the claimed composition is unclear whether the claimed amounts are intended for a lactic acid only or for a sodium lactate only or for a generic salt(s) of lactic acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Petters et al. (IDS reference; Journal of Reproduction and Fertility Supplement. 1993,

Art Unit: 1651

48:61-73) taken with Kaoru Suzuki et al. (Proc. 93rd Annual Meeting of Japanese Society of Animal Reproduction. 2000, page 68), US 5,213,979 (First et al.) and US 5,972,592 (Suarez) as explained in the prior office action and for the reasons below.

Claims are directed to a culture medium composition for in vitro produced porcine embryo culture wherein the medium composition comprises lactic acid or its salt and pyruvic acid or its salts, wherein the medium does not contain glucose, wherein the amount of lactic acid or sodium lactate is 0.25-5.5 µl/ml of a 60% solution (0.15-3 mg/ml) and wherein amount of pyruvic acid is 0.009-0.036 mg/ml. Some claims are further drawn to the culture medium that is conditioned with oviductal epithelial cells.

The reference by Petters et al. is relied upon as explained above for the disclosure of several culture medium compositions for in vitro produced porcine embryo wherein some of the medium compositions do not contain glucose and comprise salts of lactic acid and pyruvic acid. The disclosure by Petters et al. is lacking teaching about a culture medium that is conditioned with oviductal epithelial cells.

However, Kaoru Suzuki et al. teaches incorporation a medium conditioned with oviductal epithelial cells into a basal medium for in vitro produced porcine embryo (see official translation). The basal medium in the reference by Kaoru Suzuki is NCSU-37 medium that appears to contain glucose accordingly to the information in the table 1 in the reference by Petters et al.

But US 5,213,979 (First et al.) suggests incorporation of a medium conditioned with oviductal epithelial cells into the medium intended for embryos cells (see abstract; see from col. 5, lines 55, to col. 6, lines 1-6) wherein the media intended for embryos cells include the glucose

Art Unit: 1651

lacking Tyrode's lactate-pyruvate solution as well as other basic cell culture media (col. 5, lines 30-41). US 5,213,979 teaches that the use a medium conditioned with oviductal epithelial cells enhances development of embryos (col. 9, lines 65-69 to col.10, lines 1-2).

Further, the cited US 5,972,592 discloses a Tyrode' balanced salt composition that comprises salts lactic acid and pyruvic acid and that does not contain glucose (col. 9, lines 40-45) and US 5,972,592 discloses incorporation and culturing oviductal epithelium or oviductal epithelial cells in the Tyrode' balanced salt composition (col. 10, lines 10-11; col.9, line 50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add a medium conditioned with oviductal epithelial cells taught by Kaoru Suzuki et al and/or by US 5,213,979 to the glucose-lacking and lactate-pyruvate-containing medium of Petters et al. with a reasonable expectation of success in obtaining a medium for in vitro produced porcine embryo as required by the instant claims because the prior art teaches that the use a medium conditioned with oviductal epithelial cells enhances development of embryos (US 5,213,979 [First et al]) and because compositions with medium conditioned with oviductal epithelial cells are known in the prior art as adequately demonstrated by Kaoru Suzuki et al, US 5,213,979 (First et al) and US 5,972,592 (Suarez).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

With regard to the claim rejection under 35 USC § 103 applicants' arguments are directed to the exclusion of calcium lactate from the culture medium and to unexpected results provided by using of the culture medium of the instant invention.

Applicants argue that the teaching of Petters requires calcium lactate and thus, the cited reference teaches away from the claimed invention. Upon review of the cited reference it is not found true because table 1 discloses several culture media that are lacking calcium lactate and contain sodium lactate, for example: BMOC, mKRB and CZB media.

Applicants appear to argue unexpected results or beneficial effects provided by the medium composition(s) of the present invention. Yet, it is uncertain what medium composition is argued. The medium in table 1 (page 14) contains calcium and thus, calcium lactate is present in the final liquid mixture of solutions A and B even if lactate is added as sodium lactate. Moreover, the scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim. Furthermore, applicants' argument appears to be drawn to a method of culturing embryo in sequential media rather than to one and only medium composition.

No claims are allowed.

Art Unit: 1651

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

November 2, 2005



VERA AFREMOVA
PRIMARY EXAMINER